21 CFR Ch. I (4-1-13 Edition)

§571.130

to people must satisfy the requirements of subpart E of part 500 of this chapter.

[52 FR 49588, Dec. 31, 1987]

§571.130 Procedure for amending and repealing tolerances or exemptions from tolerances.

(a) The Commissioner, on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive.

(b) Any such petition shall include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or repeal. New data shall be furnished in the form specified in §571.1 for submitting petitions.

[42 FR 4717, Jan. 25, 1977; 42 FR 15676, Mar. 22, 1977]

PART 573—FOOD ADDITIVES PER-MITTED IN FEED AND DRINKING WATER OF ANIMALS

Subpart A [Reserved]

Subpart B—Food Additive Listing

Sec.	
573.120	Acrylamide-acrylic acid resin.
573.130	Aminoglycoside 3'-phospho- trans-
ferase II.	
573.140	Ammoniated cottonseed meal.
573.160	Ammoniated rice hulls.
573.170	Ammonium formate.
573.180	Anhydrous ammonia.
573.200	Condensed animal protein hydroly-
sate.	
573.220	Feed-grade biuret.
573.225	1,3-Butylene glycol.
573.240	Calcium periodate.
573.260	Calcium silicate.
573.280	Feed-grade calcium stearate and so-

Crambe meal, heat toasted.

Diammonium phosphate.

Diatomaceous earth.

Disodium EDTA. 573.380 Ethoxyquin in animal feeds.

dium stearate. 573,300 Choline xanthate.

573.310

573.320

573.340

573.360

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573.400 Ethoxyquin in certain dehydrated
   forage crops.
573.420 Ethyl cellulose.
573.440
       Ethylene dichloride.
573.450 Fermented ammoniated condensed
   whey.
573.460 Formaldehyde.
573.480
       Formic acid.
573.500
       Condensed, extracted glutamic acid
   fermentation product.
573.520 Hemicellulose extract.
573.530
       Hydrogenated corn syrup.
573.540
       Hydrolyzed leather meal.
       Iron ammonium citrate.
573.580
       Iron-choline citrate complex.
573.600
       Lignin sulfonates.
       Menadione dimethylpyrimidinol bi-
573.620
   sulfite
573.625 Menadione nicotinamide bisulfite.
573.637
       Methyl esters of conjugated linoleic
   acid (cis-9, trans-11 and trans-10, cis-12-
   octadecadienoic acids).
       Methyl esters of higher fatty acids.
573.640
573.660
       Methyl glucoside-coconut oil ester.
573.680
       Mineral oil.
573.685
        Natamycin.
573,700
        Sodium nitrite.
573.720
       Petrolatum.
573.740
       Odorless light petroleum hydro-
   carbons.
573.750
       Pichia pastoris dried yeast.
573.760
       Poloxalene.
573.780
       Polyethylene.
573.800 Polyethylene glycol (400) mono- and
   dioleate.
573.820 Polyoxyethylene glycol (400) mono-
   and dioleates.
573.840 Polysorbate 60.
573.860 Polysorbate 80.
573.870
       Poly(2-vinylpyridine-co-styrene).
573.880
       Normal propyl alcohol.
573.900
       Pyrophyllite.
573.914
       Salts of volatile fatty acids.
573.920
        Selenium.
573.940
       Silicon dioxide.
573.960
       Sorbitan monostearate.
573.980
       Taurine.
573.1000
        Verxite.
573.1010 Xanthan gum.
573.1020 Yellow prussiate of soda.
  AUTHORITY: 21 U.S.C. 321, 342, 348.
 SOURCE: 41 FR 38652, Sept. 10, 1976, unless
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Subpart A [Reserved]

Subpart B—Food Additive Listing

§ 573.120 Acrylamide-acrylic acid resin.

Acrylamide-acrylic (hydrolized polyacrylamide), only for

otherwise noted.

Food and Drug Administration, HHS

the purposes of this section as described below, may be safely used in accordance with the following prescribed conditions:

- (a) The additive is produced by polymerization of acrylamide with partial hydrolysis, or by copolymerization of acrylamide and acrylic acid with the greater part of the polymer being composed of acrylamide units.
- (b) The additive meets the following specifications:
- (1) A minimum molecular weight of 3 million.
- (2) Viscosity range: 3,000 to 6,000 centipoises at 77 °F in a 1 percent aqueous solution as determined by LVF Brookfield Viscometer or equivalent using a number 6 spindle at 20 r.p.m.
- (3) Residual acrylamide: Not more than 0.05 percent.
- (c) It is used as a thickener and suspending agent in nonmedicated aqueous suspensions intended for addition to animal feeds.

 $[41\ FR\ 38652,\ Sept.\ 10,\ 1976,\ as\ amended\ at\ 45\ FR\ 38058,\ June\ 6,\ 1980]$

§ 573.130 Aminoglycoside 3'-phosphotransferase II.

The food additive aminoglycoside 3'-phosphotransferase II may be safely used in the development of genetically modified cotton, oilseed rape, and tomatoes in accordance with the following prescribed conditions:

- (a) The food additive is the enzyme aminoglycoside 3'-phosphotransferase II (CAS Reg. No. 58943-39-8) which catalyzes the phosphorylation of certain aminoglycoside antibiotics, including kanamycin, neomycin, and gentamicin.
- (b) Aminoglycoside 3'-phosphotransferase II is encoded by the kan^r gene originally isolated from transposon Tn5 of the bacterium *Escherichia coli*.
- (c) The level of the additive does not exceed the amount reasonably required for selection of plant cells carrying the kan^r gene along with the genetic material of interest.

[59 FR 26711, May 23, 1994]

§ 573.140 Ammoniated cottonseed meal.

The food additive ammoniated cottonseed meal may be safely used in accordance with the following conditions:

- (a) The food additive is the product obtained by the treatment of cotton-seed meal with anhydrous ammonia until a pressure of 50 pounds per square inch gauge is reached.
- (b) It is used or intended for use in the feed of ruminants as a source of protein and/or as a source of nonprotein nitrogen in an amount not to exceed 20 percent of the total ration.
- (c) To assure safe use, the label and labeling of the additive and of any feed additive supplement, concentrate, or premix prepared therefrom shall bear, in addition to the other information required by the act, the following:
 - (1) The name of the additive.
- (2) The maximum percentage of equivalent crude protein from the non-protein nitrogen.
- (3) Directions for use to provide not more than 20 percent of the additive in the total ration.
 - (4) A statement:
- (i) That not more than one-third of the total protein in the feed should come from nonprotein nitrogen sources.
- (ii) That the additive is not to be given to debilitated or starved animals.
- (iii) "Warning—This feed should be used only in accordance with directions furnished on the label."

[41 FR 38652, Sept. 10, 1976, as amended at 42 FR 52397, Sept. 30, 1977]

§ 573.160 Ammoniated rice hulls.

The food additive ammoniated rice hulls may be safely used in accordance with the following prescribed conditions:

- (a) The food additive is the product obtained by the treatment of ground rice hulls with monocalcium phosphate and anhydrous ammonia at a temperature of 350 °F and a pressure of 175 pounds per square inch.
- (b) It is used or intended for use in the feed of beef cattle as a source of crude fiber and as the sole source of nonprotein nitrogen in an amount not to exceed 20 percent of the total ration.
- (c) To assure safe use of the additive, the label and labeling of the additive and of any feed additive supplement, feed additive concentrate, or feed additive premix prepared therefrom, shall contain, in addition to other information required by the act, the following: